

REMARKS

Reconsideration is respectfully requested. 1, 5, 7-8, 10-12, 14, 18-19, 21, 26, 28-29, 31-32, 53, and 56 have been amended. Claim 2-4, 6, 9, 13, 17, 20, and 55 have been cancelled. After entry of this amendment claims 1, 5, 7-8, 10-12, 14, 18-19, 21-32, 53-54, and 56 will be pending.

Examiner Interview

Applicants thank the Examiner for the phone call to Michael Ward indicating that she did not have time for an interview prior to issuing an Office Action in this case but would have time for an interview once a response to the Office Action was filed. Applicants hereby request an interview to discuss the pending claims in this case. Once the Examiner has read and considered the response to the Office Action, she is requested to telephone the undersigned at (415) 268-6846 to schedule an interview in this case.

Objections to the Drawings

The Examiner has objected to the drawings for the informalities identified in the form PTO 948. Formal drawings that correct the informalities have been submitted. Please replace the current drawings with the substitute drawings. The substitute drawings contain no new subject matter. To correct the poor quality of Figures 7(c) and 7(d), color photographs of Figures 7(a)-7(g) have been submitted with a petition in accordance with 37 CFR § 1.84(b)(2). Substitute formal drawings have been submitted for Figures 1(a)-2(c), 5(a), 5(b), and 8(a)-8(h) with enlarged font size. Finally, on those Figures that extend across more than one page, the notations "(continued on next page)" and "(continued)" have been removed. Instead, the pages have been numbered Figure 1(a)-1, Figure 1(a)-2, etc.

Objections to the Specification

The Examiner has objected to the specification for the presence of brackets and failure to comply with the sequence requirements. Due to the number of amendments required, applicants

have submitted a substitute specification and a marked up specification in accordance with 37 CFR § 1.121(3). Please replace the current specification with the substitute specification. The substitute specification includes no new matter. The specification has been amended to remove brackets, remove duplicated text in the figure legend for Figure 2 (page 17), add SEQ ID NO to comply with the sequence requirements, and add a statement in accordance with 37 CFR 1.84(a)(2)(iv), indicating that the patent or application file includes at least one color drawing.

Claim Objections

The Examiner has objected to claims 5, 8, 12 and 17 as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. Claim 17 has been cancelled and claims 5, 8, and 12 have been amended so that they are no longer multiple dependent claims.

The Examiner has objected to claims 4, 6 and 56 because they have brackets around the SEQ ID NO. Applicants have cancelled claims 4 and 6 and have amended claim 56 to remove the brackets.

In light of the amendments, applicants respectfully request that the Examiner withdraw the objections.

Claim Rejections – 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 1-14, 17-32, and 53-56 under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner states that the instant specification does not provide support for the recitation “wherein said nucleic acid molecule is not the sequence of the gene A_TM021B04.4 ...”

Applicants have amended the pending claims to remove recitations including "the gene A_TM021B04.4."

The Examiner has rejected claims 1-14, 17-32, and 53-54 under 35 U.S.C. § 112, first paragraph as allegedly failing to describe the claimed subject matter in the specification in such a way as to reasonably convey to one of ordinary skill in the art that the inventor had possession of the invention at the time that the application was filed.

Applicants respectfully disagree with the Examiner's grounds for rejection and the above statements with respect to nucleic acids that have 30% identity to SEQ ID NO:1. However, in order to facilitate prosecution in this case applicants have amended the pending claims, without prejudice or disclaimer, to remove recitations to sequence identity.

The claims as amended cover nucleic acids that hybridize under highly stringent conditions and plant nucleic acids that hybridize under moderately stringent conditions.

With respect to highly stringent hybridization, the specification clearly conveys to one of skill in the art that the inventor had possession of the claimed invention. The USPTO has published a document providing specific examples of application of the written description – "SYNOPSIS OF APPLICATION OF WRITTEN DESCRIPTION GUIDELINES". (Available online at: <http://www.uspto.gov/web/menu/written.pdf>). The SYNOPSIS has an example that is squarely on point. Example 9, pages 35-37, covers hybridization claims such as in the instant application. As in the example, applicants disclose a single cDNA, SEQ ID NO:1 which has a defined function – salt tolerance. The example states that, "The Art indicates that hybridization techniques using a known DNA as a probe under highly stringent conditions were conventional in the art at the time of filing." (SYNOPSIS at page 36) At the time of filing of the instant application, hybridization techniques were well known. Applicants claims are drawn to a genus of nucleic acids all of which must hybridize with SEQ ID NO:1 and must encode a protein with a specific activity. The Examiner has indicated that the prior art fails to teach or suggest an isolated nucleic acid of SEQ ID NO:1. Applicants disclose one species that is within the scope

of the claimed genus and therefore have actual reduction to practice of at least one disclosed species. The Example states, "a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since the highly stringent hybridization conditions in combination with the coding function of the DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention." (SYNOPSIS pages 36-37). Thus, clearly, applicants have adequately described the claimed invention.

With respect to plant nucleic acids that hybridize under moderately stringent conditions, the specification clearly conveys to one of skill in the art that the inventor had possession of the claimed invention. Switching from highly stringent to moderately stringent conditions will include less structurally related DNAs, but the claims are limited to those nucleic acids that are originally derived from plants. This limitation dramatically reduces the scope of the claimed material. One of ordinary skill in the art would recognize that the only nucleic acids originally derived from plants that would hybridize to SEQ ID NO:1 under moderate conditions would most likely be Na^+/H^+ transporters. Furthermore, the claims are limited to nucleic acids that encode Na^+/H^+ transporters. Following the teachings in this application, it would be routine for one of ordinary skill in the art to confirm that it has such activity. Thus, the moderate stringency hybridization and the requirement that the DNA sequence was originally derived from plants in combination with the coding function of the DNA would indicate to one of ordinary skill in the art that the inventor was in possession of the claimed invention.

The Examiner has rejected claims 1-14, 17-32, and 53-54 under 35 U.S.C. § 112, first paragraph as allegedly failing to enable a multitude of nucleic acids encoding any plant PNHX transporter or any plant Na^+/H^+ antiporter, that hybridize to SEQ ID NO:1; or that have 30% identity to SEQ ID NO:1, plant cells, plant parts and seeds transformed with the nucleic acids, and methods of using them to produce salt-tolerant plants.

Applicants respectfully disagree with the Examiner's grounds for rejection and the above statements with respect to nucleic acids that have 30% identity to SEQ ID NO:1. However, in order to facilitate prosecution in this case applicants have amended the pending claims, without prejudice or disclaimer, to remove recitations to sequence identity.

To satisfy the enablement requirement, a specification must contain sufficient information regarding the claimed subject matter as to enable one of ordinary skill in the art to make and use the invention as claimed. MPEP § 2164.01. This issue is addressed by asking the question of whether one of ordinary skill in the art could make and use the invention without "undue experimentation." The factors for assessing whether undue experimentation is required are listed in MPEP § 2164.01(a).

With respect to highly stringent hybridization, the specification provides specific conditions in Table 4 for highly stringent hybridization as is claimed. Testing hybridization under such defined conditions is a routine matter for one of skill in the art. Furthermore, as indicated in Example 9 of the SYNOPSIS discussed above: "a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent conditions set forth in the claim yield structurally similar DNAs." Thus, the claims are not drawn to a broad range of nucleic acids.

With respect to plant nucleic acids that hybridize under moderately stringent conditions, the specification provides specific conditions in Table 4 for moderately stringent hybridization as is claimed. Testing hybridization under such defined conditions is a routine matter for one of skill in the art. Furthermore, the claims are limited to those nucleic acids that are originally derived from plants. Thus again, the range of nucleic acids covered will be relatively limited, so the breadth of the claims is reasonably narrow.

Both types of nucleic acids are further limited by the requirement in the claim that the nucleic acid encodes an Na^+/H^+ transporter. This limitation also narrows the breadth of the claims

Furthermore, the skill in the art is high. Such work is performed by scientists at a graduate or post-doctoral level. The state of the prior art is advanced. As mentioned above, testing hybridization is a routine matter in the art. In addition, as of filing the application, transformation of plants was well developed. Expressing a gene in any particular plant is fairly predictable. The application teaches how to test for Na^+/H^+ transporter activity once the nucleic acid has been expressed in a plant. The real issue with predictability is what effect expression of any particular gene will have in a plant. This application demonstrates for the first time that overexpression of plant Na^+/H^+ transporters in plants provides salt tolerance.

In addition, the specification provides specific guidance for testing the function of nucleic acids when expressed in plants by transformation and screening of plants for salt tolerance. (See pg 56-57 and Figure 7 legend in the specification). The single example of plant transformation is sufficient to enable the scope of the claims. One of ordinary skill in the art is familiar with a number of techniques for plant transformation. The Examiner cited to one such method disclosed in Gordon-Kamm, et al. for transformation of monocots in the 103 obviousness rejection. Applicants cite to this method in the instant specification on pages 54-55.

Thus, the invention as claimed is enabled because the breadth of the claims is reasonably narrow; the state of the prior art is well developed for techniques of plant transformation and gene expression; the disclosure in the instant specification provides reasonable predictability; the level of skill in the art is high; the specification provides specific working examples, and the quantity of experimentation is reasonable.

Claim Rejections – 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 1-2, 4, 7, and 56 as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicants regard as their invention because it is unclear what “having a Na^+/H^+ transporter activity” modifies. Applicants have amended these claims so that it is clear what the recitation modifies.

The Examiner has rejected claims 2 and 3 as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicants regard as their invention because the recitation of "moderate and high stringency hybridization conditions" do not indicate hybridization and wash times. The claims have been amended so that the recitations are now part of claims 1, 18, and 53. Applicants respectfully disagree with the Examiner's rejection. The claims do not need to recite times for the hybridization and wash steps. When analyzing whether a claim is definite, the claim language must be analyzed in light of: 1) the content of the particular application disclosure; 2) the teachings of the prior art; and 3) the claim interpretation that would be given by one possessing the ordinary level of skill in the art. See MPEP § 2173.02. Hybridization is a routine procedure that one of skill in the art is quite familiar with. Thus one of ordinary skill in the art will understand how long each step should last. Furthermore, the instant specification provides an example of a hybridization experiment on page 57 and references the latest edition of Molecular Cloning: A Laboratory Manual from Cold Spring Harbor. Thus even if one of skill in the art were unable to determine appropriate times, the specification provides ample guidance that would enable one of skill in the art to determine such times.

The Examiner has rejected claim 21 as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicants regard as their invention. Applicants have amended the claim in accordance with the suggestion of the Examiner.

The Examiner has rejected claims 31-32 and 53 as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicants regard as their invention because the method is not circular. The applicants respectfully disagree. The claims produce the claimed result of the preamble. With regard to claim 31, culturing the plant cell under such conditions will produce the expression of the preamble. With regard to claim 32,

transforming the plant with the expression transgene will produce a transgenic plant as described in the preamble. With regard to claim 53, the claim has been amended to recite a "genetically transformed plant" in the preamble. Following the claimed steps will produce such a genetically transformed plant.

The Examiner has rejected claim 56 as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicants regard as their invention. Applicants have amended the claim in accordance with the suggestion of the Examiner.

In light of the above amendments and remarks, the applicants respectfully request that the examiner withdraw the rejections based upon 35 U.S.C. § 112, Second Paragraph.

Claim Rejections – 35 U.S.C. § 102

The Examiner has rejected claims 1-3, 5-6, and 9-14 as being anticipated by Brant, et al. (1997, GenBank Accession No. T51330). Applicants have amended these claims so that they are to transgenic plants containing the nucleic acid. In order to anticipate an invention, a reference must disclose all elements. Since Brant, et al. do not disclose a transgenic plant, it cannot anticipate the claimed invention.

The Examiner has rejected claims 1-3, 5-6, and 9-14 as being anticipated by Sumitomo Sieyaku KK (1993, GenBank Accession No. Q51524). Applicants have amended these claims so that they are to transgenic plants containing the nucleic acid. In order to anticipate an invention, a reference must disclose all elements. Since Sumitomo Sieyaku KK does not disclose a transgenic plant, it cannot anticipate the claimed invention.

The Examiner has rejected claims 1-3, 5-6, 8-14, 17-20, 26, and 31 as being anticipated by Hahnenberger, et al. (1996, Proc. Natl. Acad. Sci., USA 93:5031-5036). Applicants have amended claims 1, 5, 8, 10-12, and 14 so that they are to transgenic plants containing nucleic

acids. In order to anticipate an invention, a reference must disclose all elements. Since Hahnenberger, et al. do not disclose a transgenic plant, it cannot anticipate the claimed invention. Claims 19, 26 and 31 have been amended so they are to plant cells. Since Hahnenberger, et al. do not disclose a transgenic plant cell, it cannot anticipate the claimed invention. Applicants have amended claim 18 so that it covers nucleic acids that hybridize with high stringency and plant nucleic acids that hybridize with moderate stringency. One of ordinary skill in the art would not expect the *sod2* nucleic acid to hybridize to SEQ ID NO:1 at high or even moderate stringency as defined in Table 4 of applicants' specification. Furthermore, *sod2* is a yeast Na^+/H^+ transporter, not a plant transporter as is required under the claim for nucleic acids that hybridize at moderate stringency.

The Examiner has rejected claims 1-3, 5-6, 8-14, 17-24, 26-28, 20-32 and 53-54 as being anticipated by Young, et al. (WO 91/06651). Applicants have amended the claims so that they cover nucleic acids that hybridize with high stringency and plant nucleic acids that hybridize with moderate stringency. One of ordinary skill in the art would not expect the *sod2* nucleic acid to hybridize to SEQ ID NO:1 at high or even moderate stringency as defined in Table 4 of applicants' specification. Furthermore, *sod2* is a yeast Na^+/H^+ transporter, not a plant transporter as is required under the claim for nucleic acids that hybridize at moderate stringency.

Claim Rejections – 35 U.S.C. § 102

A. The Examiner's Rejections

The Examiner has rejected claims 1-3, 5-6, 8-14, 17-28, 30-32 and 53-54 under 35 U.S.C. § 103(a) as being unpatentable over Young, et al. (WO 91/06651) in view of Gordon-Kamm, et al. (1990, Plant Cell 2:603-618).

B. The Claimed Invention

The invention as claimed includes a nucleic acid that hybridizes to SEQ ID NO:1 at high stringency or a plant nucleic acid that hybridizes to SEQ ID NO:1 at moderate stringency.

C. Cited References

Young, et al. teach tobacco and *Arabidopsis* plants transformed with a gene encoding the yeast Na^+/H^+ transporter *sod2*. The Examiner has stated that the *sod2* gene would hybridize to SEQ ID NO:1. Applicants respectfully disagree. One of ordinary skill in the art would recognize that the *sod2* gene would not hybridize to SEQ ID NO:1 under moderate conditions as claimed given that the *sod2* gene has less than 35% identity with SEQ ID NO:1. Furthermore, merely functioning in a plant does not make the *sod2* gene a PNHX. In order to be a PNHX, the nucleic acid would have to have been originally derived from a plant. The *sod2* gene was originally derived from yeast, so it is not a PNHX.

D. Cited References Distinguished

35 USC 103(a) states "a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to person having ordinary skill in the art to which said subject matter pertains. The *prima facie* case must satisfy three requirements: 1) the references must teach or suggest all the claim limitations; 2) the prior art combined with general knowledge must include a suggestion or incentive to modify or combine the references; and 3) the modification or combination must have a reasonable chance of success. Furthermore, even when a *prima facie* case has been established, such case may be rebutted by evidence of "secondary considerations" including unexpected properties or results.

The Examiner fails to establish a *prima facie* case for obviousness in the above rejection. Specifically, none of the cited references teach or suggest all of the claim limitations. As discussed above, neither Young, et al. nor Gordon-Kamm, et al. teach a nucleic acid that would hybridize at high stringency or a plant nucleic acid that would hybridize at moderate stringency.

The *sod2* gene is not a plant gene, nor would it hybridize to SEQ ID NO:1 at moderate stringency.

Even assuming that the Examiner has established a *prima facie* case, such *prima facie* case is fully rebutted by the unexpected results. The instant application demonstrates that wild type PNHX genes when overexpressed in plants yield plants that salt tolerant. Young, et al. teaches away from this result. Young, et al. show that the wild type *sod2* gene does not provide salt tolerance whereas the mutant *sod2-1* gene does provide salt tolerance. (Compare Figure 3A with Figure 3B). Thus, based on Young, et al., one of ordinary skill in the art would not expect the wild type PNHX gene to provide salt tolerance to a plant.

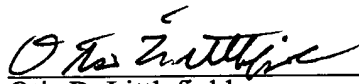
CONCLUSION

In light of the above amendments and remarks, applicants submit that the pending claims are in condition for allowance. Should there be any remaining issues that remain unresolved, the Examiner is encouraged to contact the undersigned by telephone.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 529642000200. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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